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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/388,090

08/31/99

JACKSON

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7969-082

PENNIE & EDMONDS LLP  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2711

HM12/1211

EXAMINER

DEVI, S

ART UNIT

PAPER NUMBER

1645

11

DATE MAILED:

12/11/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
**09/388,090**

Applicant(s)  
**Jackson et al.**

Examiner  
**S. Devi, Ph.D.**

Group Art Unit  
**1645**



☒ Responsive to communication(s) filed on 09/25/00.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-47 ~~is/are~~ are pending in the application.

Of the above, claim(s) 1-36 and 42-47 ~~is/are~~ are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 37-41 ~~is/are~~ are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 and 5.

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Application Number: SN 09/388,090  
Art Unit: 1645

### **DETAILED ACTION**

#### **Priority**

- 1) The instant application claims domestic priority to the provisional application, SN 60/098,685 filed 09/01/98.

#### **Preliminary Amendment**

- 2) Acknowledgment is made of Applicants' preliminary amendment filed 09/25/99 (paper no. 8), which amendment has been entered into the case.

#### **Election**

- 3) Acknowledgment is made of Applicants' election filed 09/25/99 (paper no. 8), with traverse, of invention IX, claims 38-40, in response to the restriction requirement mailed 06/06/00 (paper no. 6). The linking claims 37 and 41 are also included in this group.

Applicants traverse the requirement for restriction between inventions VII-XI on the basis that the search of SEQ ID NO: 3 would inherently and necessarily encompass search of SEQ ID NO: 1, 2, 5 and 8.

The Applicants' argument has been carefully considered, but is not persuasive. Inventions VII through XI also encompass a fragment or complement of SEQ ID numbers. 1, 3, 5 or 8 and require non-coextensive and burdensome searches for indefinite numbers of fragments and compliments of all the claimed sequences of varying length. Therefore, the requirement for restriction between inventions VII-XI made in the Office Action mailed 06/06/00 is proper and is hereby made FINAL.

#### **Status of Claims**

- 4) Claims 1-47 are pending in this application.

Claims 1-36 and 42-47 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

Claims 37-41 are under examination. An Action on the Merits for these claims is issued.

#### **Information Disclosure Statements**

Application Number: SN 09/388,090  
Art Unit: 1645

5) Acknowledgment is made of Applicants' Information Disclosure Statements filed 04/11/00 and 04/14/00 (paper no. 4 and 5). The information referred to therein has been considered and a signed copy of the same is attached to this Office Action (paper no. 11).

#### **Sequence Listing**

6) Acknowledgment is made of Applicants' CRF/sequence listing which has been entered into the case on 09/17/99 (paper no. 10).

#### **Drawings**

7) The drawings are objected to because of the problems noted by the Draftsperson in the attached Form PTO 948 (paper no. 11). Correction is required.

#### **Specification / Informalities**

8) The instant specification is objected to because of the reasons given below:

(a) The instant specification incorporates subject matter into the patent application by reference to hyperlinks. For example, see line 17, on page 3 and line 34 on page 25. However, attempts to incorporate subject matter into the patent application by reference to active hyperlinks and/or other forms of browser-executable code are considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I. Such embedded active hyperlinks and/or other forms of browser-executable code therefore require deletion.

(b) The instant specification is confusing in the characterization of certain SEQ ID numbers. For example, on page 23, lines 27 and 28, SEQ ID NO. 8 is depicted as an amino acid sequence. However, claim 38 recites SEQ ID NO: 8 as a DNA sequence. On page 23, lines 30-33, SEQ ID NO. 7 is depicted as a nucleotide sequence. However, the raw sequence listing submitted in the instant application indicates that SEQ ID NO: 7 is an amino acid sequence. Clarification/correction is requested.

(c) The use of the trademarks in the instant specification has been noted in this application. For example, see page 40, line 3: "Tween-20", and page 46, line 17: "Sephacel". Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Application Number: SN 09/388,090

Art Unit: 1645

(d) The name of the bacterial species, "E. coli", on page 44, lines 15 and 17, in the instant specification is not italicized. To be consistent with the practice in the art, it is suggested that the names of the bacterial species be italicized.

**Rejection(s) under 35 U.S.C § 102**

9) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10) Claims 37, 38 and 41 are rejected under 35 U.S.C § 102(b) as being anticipated by Lehninger AL (*Principles of Biochemistry*, Worth Publishers, Inc., New York, Chapter 27, pp. 793-836, 1982).

Claims 37, 38 and 41 encompass a fragment of the DNA having the sequence of SEQ ID NO: 3. A single nucleotide or base present in SEQ ID NO: 3 qualifies as "a fragment".

Lehninger teaches individual nucleotides or bases, adenine, guanine, cytosine and thymine that form a "fragment" of the claimed DNA or a complement of the fragment (see pages 796 and 797).

Claims 37, 38 and 41 are anticipated by Lehninger.

11) Claims 37, 38 and 41 are rejected under 35 U.S.C § 102(b) as being anticipated by Cleton-Jensen *et al.* (*Mol. Gen. Genet.* 229: 2: 206-212, 1991, see the attached sequence search report).

Claims 37, 38 and 41 encompass a fragment of the DNA having the sequence of SEQ ID NO: 3.

Cleton-Jensen *et al.* teach a "fragment" of the instantly claimed DNA (see the attached sequence search report).

Claims 37, 38 and 41 are anticipated by Cleton-Jensen *et al.*

12) Claims 37, 38 and 41 are rejected under 35 U.S.C § 102(b) as being anticipated by Matsubara *et al.* (WO 9514772).

Application Number: SN 09/388,090  
Art Unit: 1645

Matsubara *et al.* teach a fragment of a nucleotide sequence that shows 100% match with a fragment of the instantly claimed isolated DNA having SEQ ID NO: 3. See the attached sequence search report.

Claims 37, 38 and 41 are anticipated by Matsubara *et al.*

13) Claims 38-41 are rejected under 35 U.S.C § 102(a) as being anticipated by Billing-Medel *et al.* (WO 9818945, 07 May 1998, see the attached sequence search report).

It is noted that the claimed "complement" encompasses a complement that is both fully and partially complementary to the sequence of SEQ ID NO: 3.

Billing-Medel *et al.* disclose a complement of a nucleotide sequence that shows 100% match with a fragment of the instantly claimed isolated DNA having SEQ ID NO: 3 and would be expected to hybridize to the sequence of SEQ ID NO: 3 as claimed in claims 39 and 40. See the attached sequence search report.

Claims 38-41 are being anticipated by Billing-Medel *et al.*

#### Objection(s)

14) Claims 37-41 are objected to for the following reasons:

- (a) Claim 37 is objected to for lacking a preceding article between the recitation "or fragment".
- (b) Claim 37 is objected to for depending from a non-elected claim.
- (c) Claims 37-41 are objected to for including the subject matter of non-elected inventions.

#### Remarks

15) Claims 37-41 stand rejected.

16) The prior art made of record and not relied upon currently in any rejection is considered pertinent to Applicants' disclosure:

- Karkhanis *et al.* (*Infect. Immun.* 25: 635-644, 1979) teach an antigenic complex comprising a protein with a mol. wt. smear of 42,000, 44,000, 48,000 and 52,000 (see abstract).
- Normark *et al.* (WO 9213871) teach a polynucleotide encoding a polypeptide of pathogenic *Neisseria* (see entire document).

Application Number: SN 09/388,090

Art Unit: 1645

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which received papers 24 hours a day, seven days a week.

18) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 8.00 a.m. to 4.00 p.m. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



S. Devi

Patent Examiner

November 2000